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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,161	08/24/2001	Richard W. Voellmy	MDH-100XC1T	4118

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EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/939,161	VOELLMY, RICHARD W.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-91,93,94,96 and 97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 30 July 2007.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 34, 36-42, 50, 52-58, 75, 77-83 and 91 under 35 U.S.C. 112, first paragraph, for missing subject matter that is critical or essential to the practice of the invention is hereby withdrawn.

The rejection of Claims 34-91 under 35 U.S.C. 112, first paragraph, for missing subject matter that is critical or essential to the practice of the invention is hereby withdrawn.

Claims 34-91, 93, 94, 96 and 97 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to methods of reducing alopecia induced by chemotherapy, where the patient receives a heat dose on the scalp or other region susceptible to such alopecia or on the

skin of a mammal, as a means of physically inducing a stress protein response before a chemotherapeutic drug is administered. Such methods are described in the instant specification where the dose is administered at temperatures of about 39°C to about 45°C for a period of time that is between about 15 minutes to about 2 hours (See instant specification, Page 20, Lines 15-17). This dose is further described as being administered between about 2 and 24 hours prior to the administration of a chemotherapeutic agent (See instant specification, Page 20, Line 33 to Page 21, Line 2).

The examiner cannot find any indication that the instantly claimed methods may be practiced outside these parameters. As such, it is the position of the examiner that the applicant did not have possession of any invention directed to methods as described above such that it is practiced beyond the range of the parameters recited above.

Claims 34-91, 93, 94, 96 and 97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing alopecia induced by chemotherapy, where the patient receives a heat dose on the scalp or other region susceptible to such alopecia or on the skin of a mammal, at temperatures of about 39°C to about 45°C for a period of time that is between about 15 minutes to about 2 hours at a time that is between about 2 and 24 hours prior to the administration of a chemotherapeutic agent, does not reasonably provide enablement for treatment methods outside the parameters stated above. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides methods for protecting a human patient or a mammalian animal to be subjected to chemotherapy treatment of a tumor not residing in the scalp of the patient or the skin of the animal against chemotherapy-induced alopecia, comprising applying to the scalp or other region susceptible to chemotherapy-induced alopecia of a patient an effective amount of heat.

(2) The state of the prior art

Although various methods of preventing and treating chemotherapy-induced alopecia are known in the prior art, by the applicant's own disclosure, the success of such techniques are greatly influenced by a number of factors, including the gender of the patient, the half-life of the chemotherapy agent, and whether the chemotherapy treatment includes only one agent or a combination of agents. Disadvantages of the methods of the prior art include the toxicity imparted by the treatments, patient discomfort, and the administration of therapeutic compounds weeks prior to chemotherapy. Furthermore, by the applicant's own disclosure, relatively little

research has been conducted to identify the actual mechanisms of chemotherapy-induced alopecia.

(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the art is high. In methods of treating a condition, a time-dependence factor must be taken into account. Furthermore, as the Background section of the Jimenez et al. patent (previously cited in a prior art rejection) reveals, therapeutic agents must be tested for effectiveness against specific, individual chemotherapy agents.

(5) The breadth of the claims

The claims are very broad. The methods claims primarily require the application of heat to the scalp of a subject, with the heat being administered at a sufficient length of time before the administration of a chemotherapeutic drug.

(6) The amount of direction or guidance presented

In the instant specification, the applicant has disclosed that parameters, such as the amount of time the treatment is to be administered before chemotherapy and hair density before and after chemotherapy during clinical studies, help determine the intensity and duration of heat applied to a patient. Furthermore, the applicant has disclosed that such treatment parameters are to be determined empirically, using various methods, including animal modeling. In the view of the examiner, this is interpreted to say that such treatment parameters cannot be predicted or roughly estimated without conducting such testing.

(7) The presence or absence of working examples

Although the applicant has disclosed experimental procedures in detail, actual experimental results do not appear to be provided by the applicant himself. Much of the discussion of the use of a physical inducer of a stress protein response in the instant specification takes place in the future tense or in hypothetical or theoretical terms, sometimes based on the research of others in the art.

(8) The quantity of experimentation necessary

Since the treatment parameters, especially with respect to the type and amount of therapeutic agent to be used, cannot be predicted *a priori* but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine proper dosage amounts of heat, in terms of intensity and duration, to be used to treat a patient being administered a particular chemotherapeutic agent, as well as to determine the length of time between the administration of the treatment and the start of chemotherapy.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 34, 36, 39, 50, 52, 55, 75, 77 and 80 under 35 U.S.C. 102(b) as being anticipated by Li *et al.* (U.S. Patent No. 5,830,177) is hereby withdrawn.

Claim Objections

Claims 92, 95 and 98 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to Claims 34, 36-42, 50, 52-58, 75, 77-83 and 91 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER